

## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/692,282	10/23/2003	Lee Bolduc	9494.18398	7125		
26308	7590 08/17/2004		EXAM	EXAMINER		
	OMHOLZ & MANIO	ISABELLA	ISABELLA, DAVID J			
	CE BOX 26618 EE, WI 53226		ART UNIT	PAPER NUMBER		
			3738			

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application	on No.	Applicant(s)	$\rho_{\mathcal{M}}$				
Office Action Summary		10/692,28	32	BOLDUC, LEE	O.				
		Examiner		Art Unit					
		DAVID J I		3738	<u> </u>				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply									
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).									
Status									
1)🖂	Responsive to communication(s) filed on 23/10/2003.								
2a) <u></u>	This action is FINAL. 2b) This action is non-final.								
3)□									
Dispositi	on of Claims								
5) 6) 7)	4)  Claim(s) 1-32 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5)  Claim(s) is/are allowed.  6)  Claim(s) is/are rejected.  7)  Claim(s) is/are objected to.  8)  Claim(s) 1-32 are subject to restriction and/or election requirement.								
Applicat	ion Papers								
10)□	The specification is objected to by the Examine The drawing(s) filed on is/are: a) and a Applicant may not request that any objection to the Replacement drawing sheet(s) including the corrupt of the oath or declaration is objected to by the	accepted or b) he drawing(s) b rection is requir	oe held in abeyance. Se ed if the drawing(s) is ob	e 37 CFR 1.85(a). ojected to. See 37 C					
Priority (	under 35 U.S.C. § 119								
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.									
2) Notice 3) Infor	et(s) ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/er No(s)/Mail Date	08)	4) Interview Summar Paper No(s)/Mail D 5) Notice of Informal 6) Other:	ate	ГО-152)				

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, drawn to fastener, classified in class 606, subclass 153.
- II. Claims 15-28, drawn to prosthesis system, classified in class 623, subclass 1.11.
- III. Claims 29-32, drawn to surgical method, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions of group 2 and group 1 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the attachment element to have a size and configuration for coupling to the attachment site of the prosthesis. The subcombination has separate utility such as a connector for a tubular organ.

Inventions of groups 1 and 2 and 3 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the

Application/Control Number: 10/692,282 Page 3

Art Unit: 3738

fastener and the prosthesis system does not require separate steps for attachment to the targeted tissue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

## Species:

1) Prosthesis systems:

Figures 1-5;11-15

## Subspecies:

A) Prosthesis:

Figures 7A; and 7B

B) Attachment/fasteners combination:

Figures 8A; 8B; 9; 10; 18; 19; 20; and 21

C) Attachment elements 17A; 17B; 17C; 17D; and 17E

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

Art Unit: 3738

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Mr. Dan Ryan on 8/11/2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 3738

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Primary Examiner
Art Unit 3738

DJI August 11,2004